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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MATTHEWS, WILLIAM H	
ART UNIT	PAPER NUMBER
3774	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,173	AHERN, JOHN E.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38,42 and 53-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,42 and 53-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5-13-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Arguments

1. Applicant's arguments filed 5-13-08 have been fully considered but they are not persuasive.

2. Applicant contends the Berenstein device is not "sufficiently rigid to support surrounding tissue and to prevent the surrounding tissue from collapsing the scaffold structure when the scaffold structure is implanted within tissue" (remarks page 6). Examiner disagrees because Applicant's arguments pertain to the orientation of the device prior to implantation and fail to show how the device, when compacted into a dense mass (of metal, see col. 4:65- col. 5:6) would collapse under the low compressive forces of blood vessels. Berenstein disclose the device to be flexible in the deliver state in order to compact into an occlusive state and conform to the vessel, and fail to suggest the device in the implanted state would collapse in the vessel. Furthermore, Berenstein disclose larger coils which would inherently provide more rigidity as well as explicit disclosed openings when used alone (col. 3:51-56), and the devices may include a modest performed shape (lines 54-62 of col. 7). Finally, the limitation regarding collapsing is of intended use and dependent upon the tissue the device is implanted in (see MPEP 2113). It is also noted that "collapse" is interpreted to require more than mere compression. Applicant further suggests, at page 8 of the remarks, that Berenstein's device is not implantable and retained within tissue but fails to address the arguments provided in the previous office action (at page 2, paragraph 1). Applicant further suggests, at page 8 of the remarks, that Berenstein's device does not trigger an injury response. Examiner disagree because the metallic components of the device

anchor the device and would inherently trigger injury response by their mere presence in the body, or would at least be capable of meeting the product by process limitation if forced into tissue (see MPEP 2113).

3. Applicant contends Gambale is not sufficiently rigid as required by claims 38 and 42 because the device is configured to compress and expand with contraction of heart muscle (see remarks page 7). Examiner disagrees because there is a distinction between "compress" or "deform" and "collapse". Gambale describes embodiments which partially compress and fully compress (col. 3:22-35), and further describe materials to add rigidity (col. 12:49-60 and col. 14:27-31). The device of Gambale shown in Figure 2B may be considered deformed/compressed and not collapsed unlike the embodiment described at col. 3:22-35 which fully compresses, or collapses, during contraction of the myocardium. Additionally, and most important, the newly added limitation defines "sufficiently rigid" by the tissue into which the device is implanted, or functionally as addressed in MPEP 2114. Therefore, the devices of Gambale described as compressing under the contraction forces of the myocardium (but maintaining their shape between contractions, i.e. figure 2b-2c), would inherently maintain their shape and support tissue if implanted in tissues elsewhere in the body which do not contract or contract with the same force.

4. Finally, Applicant repeats that Gambale is not applicable as prior art under 35 USC 103. However, this is incorrect as Gambale is not only applicable under 102(e) but 102(a) as well because the current application and Gambale patent have different inventive entities.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 38,42,55,57,59,61,62-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Berenstein et al. US PN 6,458,119.

7. Berenstein et al disclose in c1:50-55,c3:36-50,c5:18-24,c6:48-66, and c8:45-55 an implant for treating viable tissue comprising a scaffold structure (coil or braid or chain) configured to trigger injury response and having thrombus associated with the exterior of the implant. The thrombus may be loaded with therapeutic materials including tumor inhibiting agents (chemotherapeutic agents). Regarding claims 55 and 62, either the chain embodiment or densely packed mass formed after implantation is readable on “pellet”. Column 3 lines 51-56 describe a larger coil which provides openings as required by claims 63 and 65. With regard to claims 38 and 42, the newly added limitation regarding “sufficiently rigid to support surrounding tissue" is not deemed to structurally distinguish over Berenstein as the structural limitation of “sufficiently rigid” is dependent upon the process of using the device (MPEP 2113). In

other words, the level of required rigidity is based upon the type of tissue the device is implanted in and how the device is implanted (i.e. into a pre-made cavity).

8. Claims 38,53-57,63-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Gambale et al. US PN 6,432,126.

9. Gambale et al discloses the invention as currently claimed comprising: a scaffold structure (10, 42, 60, 91, 130) implantable within in tissue, the scaffold having a geometry adapted to be retained within the tissue (see figures 5a-5d, 7a-7b 8d-8e, 9a-9b); the scaffold structure being configured to mechanically trigger and injury response in the tissue that leads to angiogenesis in the tissue (see col. 3, lines 35-36); thrombus associated with the implant, the thrombus being loaded with a therapeutic material (col. 3,lines 43-45 state that "...in addition to a thrombus of blood, the implant device may be preloaded with an angiogenic substance.." and col. 6 lines 55-61 describe "mixing"). Regarding claims 63 and 65, openings are disclosed throughout the figures. With regard to claim 64, Gambale et al. provide multiple means of meeting the limitation: "wherein the thrombus is disposed around the exterior of the device". Col. 10 line 49 - col. 11 line 2 describe a "substance" being coated or embedded in sleeve 62 which is outside of scaffold structure 64 (see figures 6A-6C). The "substance" is described as either angiogenic agents or thrombus at col. 12 lines 39-41. Embodiments including the thrombus within the scaffold are disclosed to transfer the material outside of the scaffold into adjacent tissue (see col.3 lines 16-19, col. 4 lines 1-11, and col. 13 lines 16-19). Therefore, the embodiments including internal thrombus meet the limitation because the device is designed to work with blood flow to move the thrombus to the exterior of the

scaffold. Furthermore, column 7, lines 15-28 describe external roughness features to cause an injury response which inherently leads to clotting and thrombus formation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 53, 54, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berenstein et al. USPN 6458119 as applied to claims 38,42,55,57,59,61,62 above, and further in view of Ken USPN 6113629.

Berenstein et al. meet the limitations of claims 53, 54, and 58 as described above but lack the express written disclosure of including growth factors as the therapeutic agent. Ken teaches in abstract and lines 26-41 an occlusive method utilizing growth factors within a scaffold in order to enhance occlusive properties of the device. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to use growth factors, as taught by Ken, for the therapeutic agents disclosed in the Berenstein et al. occlusive device in order to enhance the occlusive properties of the device.

Claims 56,60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berenstein et al. USPN 6458119 as applied to claims 38,42,55,57,59,61,62 above, and further in view of McGurk et al. USPN 5690671.

Berenstein et al. meet the limitations of claims 56 and 60 as described above but lack the express written disclosure of including an open cell foam structure. McGurk et al. teach in col. 4 lines 12-30 a coil embolic structure for delivery via catheter to occlude vessels as in Berenstein et al. However, lines 6-22 of col. 5 describe the addition of open cell foams to the emboli element in order to promote thrombogenic properties of the device to enhance the occlusion. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to add open cell foam structures, as taught by McGurk et al., to the emboli coils disclosed in Berenstein et al. in order to enhance the thrombogenic and occlusive properties of the coil.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
Art Unit 3774